

REMARKS

Reconsideration and withdrawal of the rejections affirmed in the Advisory Action are respectfully requested in view of the arguments presented herein. This Communication is accompanied by a Request for Continued Examination (RCE) in the instant application.

I. Amendment to the Claims

The status of the claims is as follows. Claims 1-19, 22-26, and 31-38 are amended. Claims 20, 21, and 27-30 are canceled. Claims 39-45 are as previously presented.

The amendments to the claims are to more clearly reflect the nature of the invention as directed to compositions comprising the recited polymer BTC esters, and related products formed by reaction therewith. The amendments submitted herewith introduce no matter into the application.

II. Previously Filed Amendment and Reiteration of Arguments.

Reconsideration of the arguments presented in the Amendment mailed on December 16, 2005 is respectfully requested, along with reconsideration of the Declaration by Dr. Samuel McManus and supporting Exhibits A-F submitted therewith on the same date.

In the Advisory Action, page 2, second full paragraph, the Examiner has stated the following: *"...Dolence discloses a compound represented by the formula (I) at column 2, lines 45-54. This compound is readable in the present (Applicant's) claim 1 and 6. ...The product-by-process is a product claim although produced by a different process."*

In briefly addressing the Examiner's remarks and continued ground of rejection, the Applicant respectfully points to the following. First, the Applicant acknowledges that the instant claims are indeed product-by-process claims, and that determination of patentability is based on the product itself. See, *e.g.*, the Manual of Patent Examining Procedure (MPEP), § 2113. However, the Examiner is reminded that synthetic products, and in particular polymer products where the reactants are often more complex than a

single discrete chemical entity, are defined by more than just their mere chemical formulas. As stated in *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979), “*The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product*”.

Regardless of whether the chemical formula designating the polymer BTC ester as presently claimed is the same as that disclosed in Dolence (U.S. Patent No. 5,650,234), the Examiner is completely ignoring the fact that the polymer product of the prior art (*i.e.*, the Dolence BTC ester), when considered as a whole and not merely by its chemical formula, is chemically distinct from the Applicant’s composition, as the Applicant has shown by way not only of argument, but by supporting evidence as well. See, e.g., the Declaration by Dr. Samuel McManus, and Exhibits A-F, submitted with the Amendment filed on December 16, 2005.

The Applicant has indeed met its burden in overcoming the Examiner’s rejection by not merely relying on the claimed process steps, but rather, has demonstrated in painstaking fashion that the prior art product and the compositions claimed by the Applicant are indeed different, and that the compositions as presently claimed possess an unobvious difference over the prior art, *i.e.*, the Dolence BTC ester. See, for example, MPEP §2113, and *Ex parte Gray*, 10 USPQ2d 1922.

In an effort to make clear the differences between the prior art product and the polymer BTC esters recited by the Applicant, the claims have been amended to recite a *composition* comprising a polymer BTC ester, and derivatives and products formed by reaction therewith. As is well known in the polymer arts, a polymer product *per se* is seldom a discrete chemical entity, but generally comprises, e.g., in the case of polyethylene glycol polymers, a mixture of polymers having a distribution of molecular weights due to variations in the number of ethylene oxide units (known as polydispersity), as well as detectable amounts of impurities such as PEG diol, and PEG diol-derived impurities, and the like.

As stated in the previous Amendment, and further supported by accompanying scientific evidence provided by the Applicant, the teachings of Dolence result in a PEG-BTC ester product that contains high molecular weight PEG carbonate (see Dolence, column 7, lines 53-55), while the claimed composition lacks any detectable amounts of such a compound. Thus, the compositions of the prior art and the instant application are indeed chemically distinct. Moreover, the data presented in Exhibit F demonstrate additional features distinguishing the Dolence product from the compositions as claimed. Specifically, the recrystallized (purified) product of Dolence was only 90% substituted with the desired BTC ester functionality at the PEG-hydroxy terminus, and further contained 4.3% by weight of low molecular weight PEG chain degradation products. In contrast, the claimed polymer composition was 100% substituted with the desired BTC ester functionality and contained no detectable PEG chain degradation products.

It is respectfully submitted that in contrast to the Examiner's remarks, the compositions as recited in claims 1-19, 22-26, and 31-45 are indeed chemically distinct from the teachings of Dolence, and that the Applicant has indeed met its burden by providing evidence establishing the difference(s) and unexpected properties of the claimed compositions over the prior art.

For the reasons presented above, it is submitted that all pending claims are patentable and unobvious in view of the cited art. Withdrawal of the outstanding rejection of the claims under 35 U.S.C. §103 is therefore respectfully requested.

III. Miscellaneous Formal Matters

A. Executed Declaration by Dr. Samuel McManus

A signed version of the Declaration Under 37 C.F.R. §1.132 by Dr. Samuel McManus was submitted in the instant application on January 20, 2006. An additional copy is submitted herewith for the convenience of the Examiner. Entry of the executed Declaration is respectfully requested.

B. Power of Attorney

A new Power of Attorney appointing the undersigned as an agent to prosecute the present application and to transact all business in the USPTO connected therewith is enclosed herewith.

C. Terminal Disclaimer

A new terminal disclaimer executed by the undersigned and disclaiming the terminal part of the statutory term of any patent granted on the instant application extending beyond the term of prior patents U.S. Patent Nos. 6,624,246 and 6,710,125 is enclosed herewith.

IV. Conclusion.

In view of the foregoing, the Applicant submits that the claims pending in the application are patentable over the art of record and that all other outstanding matters in the instant application have been attended to. A Notice of Allowance is therefore respectfully requested.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 493-3400.

Respectfully submitted,

Date: February 21, 2006

By:



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ON BEHALF OF NEKTAR THERAPEUTICS

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